

107TH CONGRESS
2^D SESSION

H. R. 4741

To amend title XVIII of the Social Security Act to provide affordable prescription drugs to low-income Medicare beneficiaries and stop-loss prescription drug coverage for all Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2002

Mrs. EMERSON introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide affordable prescription drugs to low-income Medicare beneficiaries and stop-loss prescription drug coverage for all Medicare beneficiaries.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; FINDINGS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Pharmacy Benefit Act of 2002”.

6 (b) FINDINGS.—The Congress finds that:

1 (1) It is essential for seniors to have access to
2 prescription medications for life and health. Pre-
3 scription medications and medication therapy man-
4 agement services are a critical component of medical
5 therapy, and are among the most cost-effective med-
6 ical interventions available in the health care system.
7 Medicare does not have an outpatient prescription
8 drug benefit for seniors. A pharmacy benefit pro-
9 gram is needed to help assure that seniors have ac-
10 cess to necessary prescription medications.

11 (2) A market-based pharmacy benefit program
12 is the best method of ensuring that medicare bene-
13 ficiaries have access to necessary prescription drugs.
14 Rather than rely on Government price controls, Con-
15 gress intends to harness the innovation and cost sav-
16 ings of the private marketplace to help meet the
17 needs of seniors.

18 (3) No prescription drug program will be truly
19 effective unless it addresses the increasing cost of
20 medications. In order to provide real relief to sen-
21 iors, a pharmacy benefit program must ensure that
22 manufacturers' price subsidies are passed on to con-
23 sumers. Manufacturers' rebates collected by phar-
24 macy benefits middlemen are not always passed on
25 to consumers. Seniors who lack coverage for pre-

1 scription medications need access to price subsidies
2 that are often available only to large pharmacy bene-
3 fits managers.

4 (4) A market-based approach will limit the tax-
5 payer funding burden of a pharmacy benefit for sen-
6 iors. However, seniors who face unusually large ex-
7 penditures for prescription medications need assist-
8 ance to purchase prescription medications. Limited
9 Federal funding of catastrophic losses is necessary
10 to protect our most vulnerable seniors.

11 (5) Seniors deserve access to quality services
12 and cost-effective drug prices at the pharmacy of
13 their choice. A pharmacy benefit for seniors will not
14 succeed without robust participation by pharmacy
15 providers. A pharmacy benefit program must provide
16 adequate payment to pharmacy providers so they are
17 able to provide the level of care that seniors need
18 and deserve.

19 (6) A truly market-based pharmacy benefit pro-
20 gram must be voluntary for all participants—manu-
21 facturers, pharmacy providers, and beneficiaries.

22 **SEC. 2. MEDICARE PHARMACY BENEFIT PROGRAM.**

23 (a) ESTABLISHMENT OF PROGRAM.—Title XVIII of
24 the Social Security Act (42 U.S.C. 1395 et seq.) is amend-

1 ed by redesignating part D as part E and by inserting
2 after part C the following new part:

3 “PART D—MEDICARE PHARMACY BENEFIT PROGRAM

4 “ESTABLISHMENT OF PROGRAM

5 “SEC. 1860. (a) PROVISION OF BENEFIT.—There is
6 established the Medicare Pharmacy Benefit Program
7 under which medicare beneficiaries who are eligible for en-
8 rollment may receive the following benefits:

9 “(1) DRUG DISCOUNTS.—Subsidies or discounts
10 from participating pharmacy providers off the price
11 of covered outpatient drugs under section 1860B.

12 “(2) CATASTROPHIC BENEFITS.—Catastrophic
13 coverage benefits under section 1860C.

14 “(3) MEDICATION REVIEW AND MANAGE-
15 MENT.—Covered medication review and medication
16 therapy management services under section
17 1860C(b).

18 “(b) VOLUNTARY PROGRAM.—Nothing in this part
19 shall be construed as requiring a medicare beneficiary, a
20 manufacturer, or a pharmacy provider to participate in
21 the program.

22 “ENROLLMENT OF ELIGIBLE BENEFICIARIES

23 “SEC. 1860A. (a) BENEFICIARY ELIGIBILITY.—

24 “(1) IN GENERAL.—Subject to paragraph (2),
25 an individual is eligible to enroll in the Medicare
26 Pharmacy Benefit Program under this part if the in-

1 dividual is entitled to benefits under part A, enrolled
2 under part B, or both.

3 “(2) INELIGIBLE INDIVIDUALS.—

4 “(A) MEDICAID ELIGIBLES.—An individual
5 may not enroll in the Medicare Pharmacy Ben-
6 efit Program under this part to the extent the
7 individual is, with respect to a year eligible for
8 medical assistance for covered outpatient drugs
9 under section 1927 under a State plan under
10 title XIX.

11 “(B) DRUG DISCOUNTS.—

12 “(i) IN GENERAL.—In the case of
13 drug subsidies and discounts from drugs of
14 a manufacturer under section 1860B, an
15 individual whose annual income exceeds
16 the applicable percentage of the Federal
17 poverty line or who does not otherwise sat-
18 isfy additional requirements established by
19 each participating manufacturer.

20 “(ii) APPLICABLE PERCENTAGE.—For
21 purposes of clause (i), the applicable per-
22 centage of the Federal poverty line is a
23 percentage established by the manufac-
24 turer of a covered outpatient drug, but in
25 no case less than 200 percent.

1 “(b) ENROLLMENT PROCESS.—

2 “(1) IN GENERAL.—The Secretary shall estab-
3 lish an open enrollment process for eligible bene-
4 ficiaries to enroll under this part.

5 “(2) PROCESSING OF ENROLLMENT APPLICA-
6 TIONS.—The Secretary shall provide that applica-
7 tions to enroll under the Medicare Pharmacy Benefit
8 Program may be collected by pharmacy providers,
9 manufacturers, or their agents. Applications col-
10 lected shall be forwarded to the appropriate Phar-
11 macy Benefit Administrator.

12 “(3) APPROVAL OF APPLICATION.—Each Phar-
13 macy Benefit Administrator shall process applica-
14 tions for enrollment and approve or reject such ap-
15 plications based upon standards established by the
16 Secretary in accordance with this part.

17 “(4) NOTICE.—Upon acceptance of an applica-
18 tion, the Pharmacy Benefit Administrator shall no-
19 tify the beneficiary and shall enter all applicable
20 data into an electronic system to allow pharmacy
21 providers to process and certify enrollment of bene-
22 ficiaries.

23 “(c) INITIAL ENROLLMENT FEE.—The Secretary
24 shall require that, prior to enrollment in the Medicare
25 Pharmacy Benefit Program, the beneficiary pay a one-

1 time initial enrollment fee in such amount as the Secretary
2 determines appropriate. Fees collected pursuant to this
3 subsection shall be deposited into the Pharmacy Benefit
4 Fund established in section 1860E to carry out this part.

5 “(d) NONDISCRIMINATION.—An eligible beneficiary
6 shall not be denied enrollment based on any health status-
7 related factor described in section 2702(a)(1) of the Public
8 Health Service Act.

9 “(e) STANDARD PHARMACY BENEFIT CARD.—Upon
10 enrollment, the Pharmacy Benefit Administrator shall
11 issue to each enrolled beneficiary a Standard Pharmacy
12 Benefit Card that conforms to the most recent standards
13 adopted by an appropriate accredited organization, as de-
14 termined by the Secretary.

15 “(f) INITIAL COVERAGE PERIOD.—An enrolled bene-
16 ficiary shall be entitled to the benefits under this part be-
17 ginning on the first day of the month following the month
18 in which such enrollment occurs.

19 “(g) TERMINATION OF COVERAGE.—

20 “(1) IN GENERAL.—A Pharmacy Benefit Ad-
21 ministrator shall terminate an enrolled beneficiary’s
22 coverage under this part if the beneficiary is no
23 longer eligible by reason of subsection (a)(2)(B).

24 “(2) NOTICE OF TERMINATION.—Upon termi-
25 nation, the Pharmacy Benefit Administrator shall

1 immediately notify the beneficiary, manufacturers,
2 and pharmacy providers.

3 “(h) PROVIDING INFORMATION TO BENE-
4 FICIARIES.—The Secretary shall provide for the broad dis-
5 semination of information to eligible beneficiaries and en-
6 rolled beneficiaries regarding enrollment under this part
7 and of the price subsidies and discounts and catastrophic
8 coverage available under this part.

9 “ACCESS TO DRUG SUBSIDIES AND DISCOUNTS

10 “SEC. 1860B. (a) IN GENERAL.—The manner in
11 which a medicare beneficiary who is enrolled in the Medi-
12 care Pharmacy Benefit Program under this part may re-
13 ceive a subsidy or a discount for the price of a covered
14 outpatient drug made available for sale by a manufacturer
15 is as follows:

16 “(1) VOLUNTARY NATURE OF SUBSIDY OR DIS-
17 COUNT.—A manufacturer may offer subsidies or dis-
18 counts for the covered outpatient drugs it makes
19 available for sale subject to the terms and conditions
20 established in a term sheet submitted by the manu-
21 facturer to the Pharmacy Benefit Administrator
22 for—

23 “(A) eligibility of the beneficiary for the
24 subsidy or discount; and

25 “(B) provisions for payment.

1 “(2) VOLUNTARY NATURE OF PHARMACIES TO
2 PARTICIPATE.—A pharmacy provider may accept or
3 reject each manufacturer’s term sheet.

4 “(3) PAYMENTS INTO PHARMACY BENEFIT
5 FUND.—A manufacturer shall make payments into
6 the Pharmacy Benefit Fund in an amount equal to
7 the aggregate amount the manufacturer agrees to
8 pay for subsidies and reimbursements to pharmacy
9 providers under the term sheet.

10 “(4) PAYMENT TO PHARMACY PROVIDER FOR
11 SUBSIDIES OR DISCOUNTS PASSED-ON TO BENE-
12 FICIARIES.—A pharmacy provider shall provide sub-
13 sidies or discounts to beneficiaries enrolled under the
14 Medicare Pharmacy Benefit Program for covered
15 outpatient drugs for which a subsidy or discount has
16 been made available by a manufacturer in the
17 amount specified in the term sheet that the phar-
18 macy provider has accepted, and shall be reimbursed
19 by the Pharmacy Benefit Administrator for each
20 such subsidy or discount passed-on to the beneficiary
21 from the Pharmacy Benefit Fund.

22 “(b) MANUFACTURER TERM SHEETS.—A manufac-
23 turer that wishes to participate in the program shall sub-
24 mit a binding term sheet to the Pharmacy Benefit Admin-
25 istrator that contains all of the terms and conditions of

1 the manufacturer's subsidies or discounts. The term sheet
2 shall describe the method of calculating any price sub-
3 sidies for beneficiaries, and the method of calculating any
4 rates that pharmacy providers may charge beneficiaries,
5 for each dosage form and strength of the manufacturer's
6 covered outpatient drugs dispensed to enrolled bene-
7 ficiaries under the program. The term sheet shall also de-
8 scribe participation requirements for beneficiaries, the du-
9 ration of the term sheet, and any other terms and condi-
10 tions of receiving any subsidies, discounts, and payments
11 made available under the term sheet. The terms and con-
12 ditions contained in the term sheets shall not impose
13 quantity restrictions of any kind on dispensing covered
14 outpatient drugs, and shall not vary based upon the class
15 of trade of the pharmacy provider or the method of deliv-
16 ering covered outpatient drugs.

17 “(c) MANUFACTURER PAYMENTS.—To the extent
18 that the manufacturer's term sheet provides that the man-
19 ufacturer will make payments to pharmacy providers
20 through the Pharmacy Benefit Administrator, the manu-
21 facturer shall make such payments into the Pharmacy
22 Benefit Fund not less frequently than each calendar quar-
23 ter, in compliance with procedures established by the Sec-
24 retary. Each calendar quarter the Pharmacy Benefit Ad-
25 ministrator shall report to each manufacturer, in a stand-

1 and reporting format established by the Secretary, infor-
2 mation on the total number of units of each dosage form
3 and strength and package size of each covered outpatient
4 drug dispensed during the preceding quarter under the
5 program. The manufacturer shall remit payments required
6 by its term sheet to that Pharmacy Benefit Administrator
7 no later than 30 days after receiving the report from the
8 Pharmacy Benefit Administrator. The Pharmacy Benefit
9 Administrator shall deposit the payments into the Phar-
10 macy Benefit Fund.

11 “(d) PHARMACY AGREEMENTS.—Any pharmacy pro-
12 vider may voluntarily enter into a provider agreement with
13 the Pharmacy Benefit Administrator for the program
14 upon such terms and conditions as the Secretary deter-
15 mines are necessary and appropriate to carry out the pur-
16 poses of this part.

17 “(e) ACCEPTANCE OR REJECTION OF TERM
18 SHEETS.—

19 “(1) ACCEPTANCE.—A pharmacy provider may
20 accept a manufacturer’s term sheet at any time dur-
21 ing the manufacturer’s participation in the program.
22 Each term sheet accepted by the pharmacy provider
23 shall become a part of the provider agreement.

24 “(2) REJECTION.—

1 “(A) NEGOTIATION.—If a pharmacy pro-
2 vider rejects a manufacturer’s term sheet, the
3 pharmacy provider and the manufacturer may
4 negotiate modifications to the pricing provisions
5 of the term sheet. If the pharmacy provider and
6 manufacturer reach an agreement pursuant to
7 such negotiations, the Pharmacy Benefit Ad-
8 ministrators shall incorporate the pricing modi-
9 fications into the electronic claims information
10 sent to the pharmacy provider whenever the
11 pharmacy provider dispenses the manufactur-
12 er’s covered outpatient drugs to enrolled bene-
13 ficiaries.

14 “(B) NOTICE TO BENEFICIARY.—If the
15 pharmacy provider rejects the manufacturer’s
16 term sheet, the pharmacy provider may inform
17 beneficiaries who are purchasing the drug prod-
18 ucts mentioned in the term sheet that the phar-
19 macy provider does not participate in the manu-
20 facturer’s subsidy program.

21 “(C) ADDITIONAL AUTHORITY.—The phar-
22 macy provider may encourage beneficiaries to
23 purchase appropriate alternatives for the manu-
24 facturer’s products after consultation with other

1 medical professionals as may be required by
2 State law.

3 “(f) PHARMACY PRICE DISCOUNTS.—

4 “(1) IN GENERAL.—Upon the presentation by
5 an enrolled beneficiary of a valid prescription for a
6 covered outpatient prescription drug product, a par-
7 ticipating pharmacy provider shall process the pre-
8 scription in accordance with the manufacturer’s
9 term sheet.

10 “(2) REAL-TIME CLAIMS PROCESSING.—Pricing
11 and payment information and other relevant provi-
12 sions of the term sheet applicable to the drug prod-
13 uct shall be calculated and communicated to the
14 pharmacy providers by the Pharmacy Benefit Ad-
15 ministrator on a real-time basis at the time a claim
16 is submitted.

17 “(g) PHARMACY CLAIMS.—

18 “(1) IN GENERAL.—A pharmacy provider shall
19 submit claims to the Pharmacy Benefit Adminis-
20 trator through an online, real-time claims processing
21 system. The Pharmacy Benefit Administrator shall
22 promptly reimburse the pharmacy provider as pro-
23 vided in the manufacturer’s term sheet, as soon as
24 practicable and in no case later than 15 days of the
25 date the claim was submitted.

1 “(2) FEES PAID BY PHARMACY BENEFIT
2 FUND.—The Pharmacy Benefit Administrator, di-
3 rectly or through an agent or otherwise, shall not
4 impose transaction charges, processing, or adminis-
5 trative fees on pharmacy providers that submit
6 claims or receive payments under the program.
7 Transactions charges, processing or administrative
8 fees shall be paid by the Pharmacy Benefit Adminis-
9 trator from the Pharmacy Benefit Fund.

10 “(h) PRICE COMPARISONS.—The Secretary shall en-
11 courage and create incentives for a pharmacy provider to
12 make available, on a voluntary basis, a price list that the
13 pharmacy provider would charge for other covered out-
14 patient drugs within the same therapeutic class.

15 “(i) PRIVATE SERVICES CONTRACTS WITH PHAR-
16 MACIES.—

17 “(1) IN GENERAL.—To the extent not prohib-
18 ited by or otherwise in conflict with any other provi-
19 sion in this title, pharmacies may privately contract
20 with manufacturers, beneficiaries or other persons to
21 provide pharmacy services to individuals upon such
22 terms and conditions as those contracting parties
23 may agree.

24 “(2) DESCRIPTION OF SERVICES.—The services
25 referred to in paragraph (1) include medication re-

1 view services, medication therapy management serv-
2 ices, medication compliance and persistence pro-
3 grams, disease state management programs for tar-
4 geted beneficiaries, refill reminders, medication mon-
5 itoring, medication therapy problem resolution, bene-
6 ficiary education regarding medication preparation
7 and administration, and other professional services
8 consistent with the applicable State’s scope of phar-
9 macy practice.

10 “CATASTROPHIC COVERAGE BENEFIT

11 “SEC. 1860C. (a) BENEFITS.—The benefits provided
12 to an eligible beneficiary under this section shall consist
13 of the following:

14 “(1) STOP-LOSS.—Payment for covered out-
15 patient drugs furnished in a year after the bene-
16 ficiary incurs in that year unreimbursed out-of-pock-
17 et costs in excess \$5,000. In the case of any cal-
18 endar year after 2003, the dollar amount in this
19 paragraph shall be adjusted each year by an amount
20 equal to the percentage increase or decrease in the
21 Consumer Price Index for medical care for the pre-
22 ceding year, as determined by the Bureau of Labor
23 Statistics.

24 “(2) MEDICATION THERAPY MANAGEMENT
25 SERVICES.—Payment for covered medication therapy
26 management services and other professional services

1 furnished by a pharmacy provider in accordance
2 with the provisions of this part.

3 “(b) MEDICATION REVIEW AND MEDICATION THER-
4 APY MANAGEMENT.—

5 “(1) PURPOSE.—To help reduce overall medical
6 costs, the Secretary shall implement a medication re-
7 view and medication therapy management services
8 program designed to ensure that covered outpatient
9 drugs are used appropriately to achieve therapeutic
10 goals and reduce the risk of adverse events, includ-
11 ing adverse drug interactions.

12 “(2) SERVICES DESCRIBED.—Covered medica-
13 tion review and medication therapy management
14 services shall be treated as treatment activities for
15 purposes of applying part C of title XI, and shall
16 include—

17 “(A) services or programs provided by par-
18 ticipating pharmacy providers which are de-
19 signed to—

20 “(i) assure that medications are used
21 appropriately by beneficiaries;

22 “(ii) enhance beneficiaries’ under-
23 standing of the appropriate use of medica-
24 tions through beneficiary education, coun-
25 seling, and other appropriate means;

1 “(iii) increase beneficiaries’ adherence
2 with prescription medication regimens
3 through medication refill reminders, special
4 packaging, and other appropriate means;
5 “(iv) reduce the risk of potential ad-
6 verse events associated with medications;
7 and
8 “(v) reduce the need for other costly
9 medical services through better manage-
10 ment of medication therapy; and
11 “(B) services offered by pharmacy pro-
12 viders involving counseling, case management,
13 disease management, patient training and edu-
14 cation, medication refill reminders, medication
15 therapy management and problem resolution,
16 annual medication review assessments of all
17 medications currently used by a beneficiary to
18 identify potential adverse interactions or to
19 identify the need for additional medication
20 therapies, and such other professional services
21 that enhance the use of prescription medica-
22 tions, consistent with the scope of the practice
23 of pharmacy as defined by applicable State law.

1 “(2) PROGRAM OPERATION.—Any medication
2 therapy management program established under this
3 section must—

4 “(A) identify and provide medication ther-
5 apy management services to beneficiaries at
6 risk for potential medication problems, such as
7 beneficiaries taking multiple medications and
8 beneficiaries with complex or chronic medical
9 conditions;

10 “(B) be developed and structured in co-
11 operation with organizations representing par-
12 ticipating pharmacy providers, including identi-
13 fying those medication therapy management
14 services that will be provided, as well as pay-
15 ment mechanisms for these services; and

16 “(C) provide for ongoing evaluation and
17 documentation of these services in improving
18 quality of care and reducing health care costs.

19 “(c) PAYMENTS FOR COVERED OUTPATIENT
20 DRUGS.—For each covered outpatient drug dispensed to
21 an enrolled beneficiary by a participating pharmacy pro-
22 vider under this section, the Pharmacy Benefit Adminis-
23 trator shall pay the pharmacy provider an amount equal
24 to the lesser of—

1 “(1) the pharmacy provider’s usual and cus-
2 tomary retail price, without regard to any discount
3 otherwise applicable, for the covered outpatient drug
4 that the pharmacy provider ordinarily charges cus-
5 tomers who do not have private or Federal or State
6 financed prescription drug coverage; or

7 “(2) the sum of the applicable drug product re-
8 imbursement rate under subparagraph (A) and the
9 administrative allowance under subparagraph (B),
10 but in no case less than the minimum rate under
11 subparagraph (C), as follows:

12 “(A) DRUG PRODUCT REIMBURSEMENT.—

13 “(i) GENERICS.—For covered out-
14 patient drugs that are noninnovator mul-
15 tiple source drugs, the drug product reim-
16 bursement rate shall equal the maximum
17 payment amount calculated under section
18 1927.

19 “(ii) OTHER DRUGS.—For a drug
20 other than a drug described in clause (i),
21 the drug product reimbursement shall
22 equal 110 percent of the most current
23 wholesale acquisition cost of the drug prod-
24 uct as reported by the manufacturer.

1 “(B) ADMINISTRATIVE ALLOWANCE.—For
2 calendar year 2003, an administrative allowance
3 of \$7.00 per prescription shall be paid as reim-
4 bursement for costs associated with storing,
5 preparing, and dispensing covered outpatient
6 drugs, operating and staffing pharmacy loca-
7 tions, and other direct and indirect costs of pro-
8 viding covered outpatient drugs under this part,
9 as well as to provide an incentive to participate
10 in the program.

11 “(C) ADJUSTMENT FOR INFLATION.—For
12 a year after 2003, the administrative allowance
13 shall be adjusted annually based on the percent-
14 age increase or decrease in the Consumer Price
15 Index for medical care for the preceding year,
16 as calculated by the Bureau of Labor Statistics.

17 “(d) PAYMENTS FOR MEDICATION REVIEW AND
18 MEDICATION THERAPY MANAGEMENT.—For covered
19 medication review and medication therapy management
20 services provided to an enrolled beneficiary by a pharmacy
21 provider, the Pharmacy Benefit Administrator shall make
22 payments to the pharmacy provider in amounts estab-
23 lished by the Secretary that—

1 “(1) are reasonable and adequate to cover all
2 direct and indirect overhead and other costs of fur-
3 nishing the services;

4 “(2) do not vary by size, type, or corporate
5 structure of pharmacy provider;

6 “(3) do not exceed the pharmacy provider’s
7 usual and customary retail charges that the phar-
8 macy provider ordinarily charges customers who do
9 not have private or Government financed coverage
10 with respect to such benefits; and

11 “(4) recognize and provide appropriate payment
12 incentives for individual pharmacy providers located
13 in rural and underserved areas, as the Secretary
14 may define.

15 “(e) MANUFACTURER PAYMENTS.—

16 “(1) IN GENERAL.—The Pharmacy Benefit Ad-
17 ministrators shall only make payment under this part
18 for innovator multiple source drugs or single source
19 drugs (as defined in clauses (ii) and (iv), respec-
20 tively, of section 1927(k)(7)(A)) for which payment
21 may be made under this part of a manufacturer if
22 that manufacturer has entered into and has in effect
23 an agreement with the Pharmacy Benefit Adminis-
24 trators that requires the manufacturer to make peri-
25 odic payments in the amount described in this sub-

1 section. A payment agreement shall be effective for
2 an initial period of not less than 1 year and shall be
3 automatically renewed for a period of not less than
4 1 year.

5 “(2) AMOUNT OF PAYMENT.—

6 “(A) IN GENERAL.—The payment amount
7 for a covered outpatient drug furnished under
8 this part shall be equal to not less than the sum
9 of the basic rebate amount (determined under
10 subparagraph (B)) for each dosage form and
11 strength of such drug increased by the amount
12 of the inflation adjustment rebate (determined
13 under subparagraph (C)) for each dosage form
14 and strength of such drug.

15 “(B) BASIC REBATE AMOUNT.—The basic
16 rebate amount shall be equal to the product of
17 the total number of units of each dosage form
18 and strength paid for by the Pharmacy Benefit
19 Administrator in the payment period (as de-
20 fined in section 1927(b)), and the average man-
21 ufacturer’s price (as defined in section 1860)
22 for the quarter for the dosage form and
23 strength of the covered outpatient drug minus
24 not less than 18 percent of the average manu-
25 facturer’s price for the quarter, or such amount

1 as determined by the Secretary through nego-
2 tiations with the manufacturer of such drug.

3 “(C) INFLATION ADJUSTMENT AMOUNT.—

4 The amount of the basic rebate payment shall
5 be increased by an amount equal to the product
6 of the number of units of each dosage form and
7 strength paid for by the Pharmacy Benefit Ad-
8 ministrator in the payment period and the
9 amount by which the average manufacturer’s
10 price for such drug and dosage form and
11 strength for the calendar quarter increased in
12 excess of the percentage by which the consumer
13 price index for all urban consumers increased
14 during the calendar quarter.

15 “(3) PHARMACY BENEFIT ADMINISTRATOR RE-
16 SPONSIBILITY.—The Pharmacy Benefit Adminis-
17 trator shall report to each manufacturer not later
18 than 60 days after the end of each payment period
19 and in a form consistent with a standard reporting
20 format established by the Secretary, information on
21 the total number of units of each dosage form and
22 strength and package size of each covered outpatient
23 drug dispensed in the quarter for which payment
24 was made under the program during the period, and

1 shall promptly transmit a copy of such report to the
2 Secretary.

3 “(4) MANUFACTURER RESPONSIBILITY.—The
4 manufacturer shall remit payments to the Pharmacy
5 Benefit Administrator not later than 30 days after
6 receiving information from the Pharmacy Benefit
7 Administrator on the total number of units of each
8 dosage form and strength of the manufacturer’s
9 drugs paid for by the Pharmacy Benefit Adminis-
10 trator in the quarter.

11 “(5) COLLECTION OF PAYMENTS.—The Phar-
12 macy Benefit Administrator shall deposit the pay-
13 ments collected under this subsection from manufac-
14 turers in the Pharmacy Benefit Fund, and shall use
15 the payments for program purposes.

16 “(f) COST AND UTILIZATION MANAGEMENT; QUAL-
17 ITY ASSURANCE.—In addition to other incentives provided
18 to pharmacy providers under this part, in connection with
19 catastrophic coverage benefits provided under this section,
20 the Secretary may establish and create incentives for phar-
21 macies to participate in—

22 “(1) an effective cost and drug utilization man-
23 agement program, including appropriate incentives
24 to promote appropriate use of generic drugs in order
25 to maximize program savings;

1 “(2) quality assurance measures and systems to
2 reduce medical errors and adverse drug interactions,
3 including a medication therapy management pro-
4 gram; and

5 “(3) a program to control fraud, abuse, and
6 waste.

7 “(g) NONDISCRIMINATION.—The payments made to
8 pharmacy providers under this section for covered out-
9 patient drugs shall not vary based upon the identity or
10 class of trade of the pharmacy provider or the method of
11 delivering the covered outpatient drugs.

12 “PHARMACY BENEFIT ADMINISTRATOR

13 “SEC. 1860D. (a) SELECTION.—

14 “(1) ESTABLISHMENT OF BIDDING PROCESS.—
15 The Secretary shall establish a process under which
16 the Secretary accepts bids and awards a contract to
17 one or more Pharmacy Benefit Administrators to
18 administer the benefits under this part for eligible
19 beneficiaries. Each entity desiring to enter into the
20 contract under this part shall submit a bid to the
21 Secretary at such time, in such manner, and accom-
22 panied by such information as the Secretary may
23 reasonably require.

24 “(2) AWARDING OF CONTRACT.—The Secretary
25 shall, consistent with the requirements of this part
26 and the goal of containing program costs, award

1 contracts to one or more entities to serve as Phar-
2 macy Benefit Administrators.

3 “(3) ELIGIBLE ENTITIES.—An entity eligible
4 for consideration by the Secretary as the Pharmacy
5 Benefit Administrator shall meet at least the fol-
6 lowing criteria:

7 “(A) PERFORMANCE.—The entity shall
8 have sufficient expertise, personnel, and re-
9 sources to perform the contracted benefit ad-
10 ministrations. The entity shall be subject to
11 such review as required by the Secretary, both
12 prior to issuing a contract under this part and
13 in review of performance administering con-
14 tracts under this part, including audits as ap-
15 propriate.

16 “(B) FINANCIAL INTEGRITY.—The entity
17 and its officers, directors, agents, and man-
18 aging employees shall have a satisfactory record
19 of professional competence and professional and
20 financial integrity, and the entity shall have
21 adequate financial resources to perform services
22 under the contract without risk of insolvency.

23 “(C) CAPABILITY TO MAINTAIN
24 RECORDS.—The entity shall have systems to
25 maintain adequate records, and afford the Sec-

1 retary access to such records (including for
2 audit purposes).

3 “(D) COST AND PRICING DATA.—The enti-
4 ty shall submit to the Secretary as part of its
5 bid submission all relevant cost and pricing
6 data which shall include all fees charged by the
7 entity for performing the administrative func-
8 tions pursuant to any competitively bid contract
9 awarded to the Pharmacy Benefit Adminis-
10 trator under this section, plus any and all ad-
11 ministrative fees or other payments received by
12 the entity from any entity for any goods or
13 services that relate directly or indirectly to the
14 program.

15 “(E) CAPABILITY TO GENERATE RE-
16 PORTS.—The entity shall have systems to make
17 such reports and submissions of financial and
18 utilization data as the Secretary may require,
19 including but not limited to, reports describing
20 the nature and type of manufacturers’ pay-
21 ments received by the Pharmacy Benefit Fund.

22 “(F) CONFLICT OF INTEREST.—The entity
23 shall have no conflict of interest in performing
24 the duties of a Pharmacy Benefit Administrator
25 under this part, such as a conflict of interest

1 may arise if the entity owns or controls, or is
2 owned or controlled by, a manufacturer or
3 pharmacy provider that participates in the pro-
4 gram.

5 “(b) DUTIES.—The Pharmacy Benefit Administrator
6 shall perform the following administrative functions—

7 “(1) receive, disburse, and account for funds in
8 making payments to participating pharmacy pro-
9 viders under this part;

10 “(2) assure that proper payments are made
11 under this part;

12 “(3) serve as a channel of communication of eli-
13 gibility and coverage information to beneficiaries and
14 pharmacy providers;

15 “(4) provide the information and computer sys-
16 tem support, either directly or through a contract
17 with an outside entity, for participating pharmacy
18 providers to conduct a drug utilization review pro-
19 gram conforming to the standards established by
20 section 1927(g)(2), with modifications as the Sec-
21 retary determines by regulation to be appropriate;

22 “(5) conduct activities to prevent fraud, abuse,
23 and waste, in accordance with existing law or regula-
24 tions promulgated by the Secretary;

1 “(6) monitor and collect payments from partici-
2 pating manufacturers as required by this part;

3 “(7) process applications, determine eligibility,
4 and maintain eligibility files for beneficiaries as di-
5 rected by the Secretary;

6 “(8) facilitate and support contracts between
7 pharmacy providers and manufacturers pursuant to
8 sections 1860B and 1860C;

9 “(9) issue Standard Pharmacy Benefits Cards
10 to enrolled beneficiaries upon approved enrollment
11 and thereafter as necessary;

12 “(10) execute agreements with manufacturers
13 and pharmacy providers;

14 “(11) comply with all standards applicable to
15 covered entities under the administrative simplifica-
16 tion provisions of the Health Insurance Portability
17 and Accountability Act of 1996;

18 “(12) operate a service center available all day
19 every day to answer questions and resolve problems
20 presented by beneficiaries and pharmacy providers;
21 and

22 “(13) resolve coordination of benefits issues to
23 facilitate the secondary payer status of the program,
24 pursuant to rules and procedures established by the
25 Secretary.

1 “(c) LIMITED FUNCTIONS OF PHARMACY BENEFIT
2 ADMINISTRATOR.—The role of the Pharmacy Benefit Ad-
3 ministrator shall be purely administrative. The Secretary
4 may receive, review, and resolve complaints from bene-
5 ficiaries, pharmacy providers, and manufacturers alleging
6 that the Pharmacy Benefit Administrator has exceeded or
7 abused its authority. The Secretary shall not contract with
8 the Pharmacy Benefit Administrator to—

9 “(1) negotiate or make determinations of the
10 rates and amounts of payments to be made to phar-
11 macy providers under this part;

12 “(2) make determinations of any limitations on
13 covered benefits, such as the nature, scope, choice,
14 or amount of benefits available, including but not
15 limited to, prior authorization or limitations on the
16 quantity or days supply of covered outpatient drugs
17 dispensed by pharmacy providers; or

18 “(3) manage patient care or clinical aspects of
19 the program, or to otherwise practice medicine or
20 pharmacy.

21 “(d) CONFIDENTIALITY.—The Pharmacy Benefit Ad-
22 ministrator shall not own, use, or disclose patient informa-
23 tion or the business or proprietary information of manu-
24 facturers or pharmacy providers, and shall not contact or
25 communicate with beneficiaries, other than as necessary

1 to perform the duties enumerated in this part, except as
2 otherwise required by law.

3 “(e) ADMINISTRATIVE FEES.—

4 “(1) PAYMENT TO PHARMACY BENEFIT ADMIN-
5 ISTRATOR.—The Secretary shall establish procedures
6 for paying administrative fees to the Pharmacy Ben-
7 efit Administrator under a contract entered into
8 under this part for costs associated with processing
9 enrollment applications, determining eligibility,
10 issuing Standard Pharmacy Benefits Cards, col-
11 lecting subsidies and payments from manufacturers
12 and disbursing them to pharmacy providers, proc-
13 essing individual prescription claims, administering
14 the catastrophic benefit under this part, and per-
15 forming the other administrative functions required
16 by this part. The administrative fees shall be nego-
17 tiated by the Secretary.

18 “(2) NO ENTITLEMENT TO MANUFACTURER
19 SUBSIDIES.—The payments made by manufacturers
20 under this part are intended to reduce the costs in-
21 curred by enrolled beneficiaries, and the Pharmacy
22 Benefit Administrator is not entitled to a portion of
23 those payments. The Pharmacy Benefit Adminis-
24 trator shall be prohibited from accepting any remu-

1 neration from a manufacturer for any services di-
2 rectly or indirectly related to the program.

3 “PHARMACY BENEFITS FUND

4 “SEC. 1860E.

5 “(a) PHARMACY BENEFIT FUND.—There is estab-
6 lished within the Federal Supplementary Medical Insur-
7 ance Trust Fund established under section 1841 an ac-
8 count to be known as the “Pharmacy Benefit Fund”.

9 “(b) DEPOSITS.—There shall be deposited into the
10 Pharmacy Benefit Fund—

11 “(1) subsidy or discounts payments from manu-
12 facturers under this part,

13 “(2) amounts appropriated to the Pharmacy
14 Benefit Fund.

15 Interest on Fund balances shall accrue to the fund.

16 “(c) PAYMENT OF BENEFITS.—Surplus assets of the
17 Pharmacy Benefit Fund shall be used for the benefit of
18 the program. The assets of the Fund shall be used to—

19 “(1) reimburse pharmacy providers for price
20 subsidies, medication review and medication therapy
21 management services, and catastrophic coverage
22 benefits provided to enrolled beneficiaries under this
23 part; and

24 “(2) reimburse the Pharmacy Benefits Adminis-
25 trator for its administrative costs as provided in sec-
26 tion 1860D.

1 “(d) FINANCING AND APPROPRIATIONS.—

2 “(1) FINANCING.—The costs of providing bene-
3 fits under this part shall be payable primarily from
4 the Pharmacy Benefit Fund, and secondarily from
5 the Federal Supplementary Medical Insurance Trust
6 Fund established under section 1841.

7 “(2) ONGOING APPROPRIATIONS.—There are
8 authorized to be appropriated to the Pharmacy Ben-
9 efit Fund from time to time, out of any moneys in
10 the Treasury not otherwise appropriated, amounts
11 equal to the amount by which the costs of providing
12 the payments and benefits under this part exceed
13 the enrollment fees and manufacturer payments col-
14 lected under this part.

15 “(e) SECONDARY PAYER PROVISIONS.—The provi-
16 sions of section 1862(b) shall apply to the benefits pro-
17 vided under this part.

18 “(f) EXCLUSION OF DRUG PRICES FROM BEST
19 PRICE DETERMINATIONS.—

20 “(1) STATE MEDICAID PROGRAMS.—Prices for
21 covered outpatient drugs established or offered
22 under this part shall not be considered for purposes
23 of calculating reimbursement from States to phar-
24 macy providers for outpatient drugs or services fur-
25 nished to individuals under title XIX of this Act.

1 “(2) MEDICAID DRUG REBATE PROGRAM.—Any
2 prices for covered outpatient drugs established or of-
3 fered under this part shall be excluded from the defi-
4 nition of ‘best price’ contained in section
5 1927(e)(1)(C).

6 “DEFINITIONS

7 “SEC. 1860F. In this part:

8 “(1) AVERAGE MANUFACTURERS’ PRICE.—The
9 term ‘average manufacturers’ price’ means, with re-
10 spect to a prescription drug of a manufacturer pro-
11 vided under this part for a calendar quarter, the av-
12 erage unit price paid to the manufacturer by whole-
13 salers for drugs distributed to the retail pharmacy
14 class of trade (excluding direct sales to hospitals,
15 health maintenance organizations, and wholesalers
16 where the drug is relabeled under the distributor’s
17 national drug code). Average manufacturers’ price
18 includes cash discounts allowed and all other price
19 reductions that reduce the actual price paid.

20 “(2) COVERED OUTPATIENT DRUG.—

21 “(A) IN GENERAL.—Subject to paragraph
22 (2), the term ‘covered outpatient prescription
23 drug’ means—

24 “(i) a drug or biological that may be
25 dispensed only upon a prescription;

1 “(ii) insulin certified under section
2 506 of the Federal Food, Drug, and Cos-
3 metic Act, and needles, syringes, and dis-
4 posable pumps for the administration of
5 such insulin; and

6 “(iii) such nonprescription drugs as
7 defined under section 503 of the Federal
8 Food, Drug, and Cosmetic Act that are
9 prescribed and determined medically nec-
10 essary by a physician or other health care
11 provider licensed by the State to prescribe
12 medications.

13 “(B) EXCLUSION OF COSMETIC AGENTS
14 AND FERTILITY AGENTS.—For purposes of cat-
15 astrophic coverage under section 1860D, the
16 term ‘covered outpatient drugs’ does not include
17 medications or classes of outpatient prescription
18 drugs described in subparagraphs (B) and (C)
19 of section 1927(d)(2).

20 “(3) MANUFACTURER.—the term ‘manufac-
21 turer’ means any entity which is engaged in the pro-
22 duction, preparation, propagation, conversion, or
23 processing of prescription drug products, but such
24 term does not include a wholesale distributor or a
25 pharmacy provider that compounds, repackages, re-

1 labels, dispenses, or distributes prescription drug
2 products.

3 “(4) PHARMACY PROVIDER.—The term ‘phar-
4 macy provider’ means any private sector pharmacist
5 or pharmacy that is authorized by applicable State
6 agencies to engage in the practice of pharmacy or
7 operate a pharmacy.”.

8 (b) EXCLUSION OF PART D COSTS FROM DETER-
9 MINATION OF PART B MONTHLY PREMIUM.—

10 Section 1839(g) of the Social Security Act (42 U.S.C.
11 1395r(g)) is amended by inserting before the period the
12 following: “, or attributable to the Medicare Pharmacy
13 Benefit Program under part D”.

14 (c) CONFORMING REFERENCES TO PREVIOUS PART
15 D.—Any reference in law (in effect before the date of en-
16 actment of this Act) to part D of title XVIII of the Social
17 Security Act is deemed to be a reference to part E of such
18 title (as in effect after such date).

19 (d) EFFECTIVE DATE.—The amendments made by
20 this section shall first apply on January 2003.

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